

Structured Product Labeling (SPL) OTC Sub-team Teleconference









May 4, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or if you are listed and were not on the call) should contact Marcia.

-  Cheryl Blik, Teva Pharmaceuticals, USA
-  Richard Brandt, Quark, Inc.
-  David Brown, Colgate Palmolive Company
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Michele Hewitt, Sandoz Inc., Broomfield
-  Mike Koenig, FDA
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Gayle Lempka, Watson Laboratories, Inc.
-  Carolyn Lindsay, Cardinal Health
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
-  Devon Morgan, Perrigo Company (sub-team co-leader)
-  Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
-  Jeff Poisson, i4i
-  Eva Rivera, Glemser Technologies Corporation
-  Nick Romano, Novartis Consumer Healthcare
-  Gary Saner, Reed Technology and Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratories, Inc.
-  Lonnie Smith, FDA

-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Karen Stith, Image Solutions
-  Carl Strotz, Wyeth Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Craig Trautman, Intagras
-  Mark Vranich, Blistex, Inc.
-  Ann Vu, FDA
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: May 18, 2009 (unless cancelled)

III. FDA Data Council Issues

- A. Updates to Data Council Web Pages (as of May 4, 2009) – Please <http://www.fda.gov/oc/datacouncil/> for the latest information. Interested parties can sign up to receive automatic updates whenever the website is updated directly from the agency (link on the main Data Council page).

SPL web page (<http://www.fda.gov/oc/datacouncil/spl.html>) – Updated to include links to:

1. UNII list with synonyms <http://www.fda.gov/oc/datacouncil/UNIIs.zip>
2. XML terminology files with only preferred terms for substances and UNIIIs http://www.fda.gov/oc/datacouncil/terminology_lists.zip
3. Data Standards Council's SPL terminology web page <http://internet-dev.fda.gov/oc/datacouncil/term.html#marcat>
Terminology zip file http://www.fda.gov/oc/datacouncil/terminology_lists.zip
Point of clarification about when the pre-market application categories should be used: The four marketing categories (referenced

on the webpage) are associated with devices and should be used in SPL only when a device is the “lead” for listing drug/device combination products.

4. “Validators” webpage (validation tool that can be used to validate SPL Release 4 documents prior to submission to the FDA)
<http://www.fda.gov/oc/datacouncil/validate.html>

B. National Library of Medicine (NLM) – New feature on DailyMed website: Product Identification System <http://dailymed.nlm.nih.gov/dailymed/prdsearch.cfm>

IV. Sub-team Member Question/s for Discussion

Q1. FDA is requiring unit strengths to be expressed in metrics or some other ratio but cannot be represented by percent (%). **Will this be a problem for OTC (and Vet Med) products?**

Is there straightforward methodology for converting % into ratios?

- ✓ In the Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing (Section 3.12, page 11), there are guidelines to express product strength for active ingredients.
http://www.fda.gov/oc/datacouncil/SPL_r4_IG_v1.0.pdf

How would units for ounces and fluid ounces be converted to grams (depending on the substances)?

- ✓ Marcia Howard will inquire if fluid ounces will be added to the list of options.

Does packaging need to be changed to match the listing?

- ✓ Marcia will confirm that packaging does NOT need to match the listing requirements.

Q2. How should citations be listed for products falling under the monograph system that contain multiple ingredients?

- ✓ It was recommended that the citations be noted according to 21 CFR 341
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>.
It was also noted that the part number may be adequate for the citation.

Q3. Are active pharmaceutical ingredients (APIs) required to have NDC numbers?

- ✓ A sub-team member (from an API supplier company) indicated that NDC numbers are required for APIs imported to the United States.

Sub-team members are encouraged to send any questions or discussion topics for the next call to Paula Markert (GSK), Devon Morgan (Perrigo) and Marcia Howard (CHPA) at their convenience.

V. Upcoming SPL Educational Forums

- A. FDA face-to-face meeting on June 10, 2009 (attendance will be limited to available seats)
- B. FDA SPL R4 Training Session 9 (webinars)
- C. DIA SPL Workshop (Date and Location TBD; tentatively August 2009, Philadelphia, PA)

Based on early planning activities, there will be an SPL tutorial offered on the first day of the meeting followed by a second day of “hot topics”, early lessons learned, etc. There will be a vendor showcase throughout the meeting for those interested in speaking with potential service providers on location. Additional details will be given as they become available but sub-team members are asked to send any ideas for “hot topics” to Paula, Devon, and Marcia Howard for program consideration.

- D. SPL “Press Release”

A general announcement about SPL will be made available within the next two weeks. This release will be posted to the various trade association websites (as permitted) and the Wiki page. However, it will be general enough that sub-team members can use in the outreach to clients and interested parties, as well as post to individual web pages as appropriate.

MDH/05-04-09

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Last Revised: May 4, 2009 Sent: May 4, 2009